

INVITATION

The Blood Sciences Department at Leeds Teaching Hospitals NHS Trust are interested in updating the normal values of commonly used blood tests. Knowing these values will help our laboratory and doctors decide whether patient results are abnormal. To do this we need healthy volunteers to donate blood samples. We are inviting you to help us with a research project which we hope will enable us derive the reference values of common blood tests among healthy volunteers in the Yorkshire region. The following letter explains the research in more detail and what it would involve for you. Please take the time to read through the following information carefully and discuss it with friends, relatives or your GP if you wish. Please ask us if there is anything that is not clear or if you would like more information (Dr Julian H Barth or Dr Ahai Luvai at Leeds Biochemistry).

WHAT IS THE PURPOSE OF THE STUDY?

As you may have already experienced, clinical care in the NHS is now often shared across several hospital sites. There has been some concern that results from different laboratories may have significant differences which could mislead doctors as they make decisions based on these tests. Our research aims to find out what our reference limits in the Yorkshire region are and what impact testing at different laboratories has.

WHY HAVE I BEEN CHOSEN?

We are inviting any healthy people to take part in our study. You must be over 18 years of age, not taking any medications, not breast feeding or pregnant and not suffering from any serious medical condition such as diabetes, cancer or heart disease.

DO I HAVE TO TAKE PART?

We do hope you will be able to find the time to help us, but you are under no obligation to take part in this research. If you do decide now that you would like to help with the study then you will be free to leave it at any point and without having to give a reason.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

If you would like to take part, then you will need to come to our testing centres at either the Leeds General Infirmary or St James University Hospital on one occasion only. The visit will take about thirty to forty five minutes. We will explain the study to you in more detail and you will have the opportunity to ask any questions that you may have. We will also ask you to sign a consent form saying that you agree to take part, a copy of which will be given to you to keep for your own records. Providing you are happy to proceed, we will then ask you to complete a short interview questionnaire about your general health. We will measure your pulse, blood pressure, height and weight. We will then collect 1 egg cup full (40mL) of blood from your vein into a number of blood sample tubes. This will be similar to the usual blood tests you may have had at your GPs or in hospital before. The blood samples will be analysed in selected laboratories in the region for commonly used tests such as cholesterol, hormones, blood sugar and so on. After the blood tests we will assess you to make sure that you are fit to return home. A copy of your results will be sent to you and to your GP if you wish. We will keep a small blood sample for future tests that we may wish to have done.

WHAT ARE THE SIDE EFFECTS OF TAKING PART?

We do not expect that you will experience any side effect as no medication will be administered to you.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

We do not expect that you will experience any significant harm from taking part in this study. However, some people can get bruising at the needle site while others may feel faint at the site of blood or if they fear needles.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

You will benefit by having a copy of your blood tests sent to you and to your GP if you wish.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

All the information that is collected about you during the course of the research will be kept strictly confidential. Nobody from outside the research team will be allowed access to any information that might identify you. We will only tell your GP that you are involved in this study if you allow us to or if we find seriously abnormal results in your blood tests. Once we have sent you your results, we will anonymise them so that no results can be traced back to you.

WHAT WILL HAPPEN TO ANY SAMPLES I GIVE?

Your blood sample will be distributed between the participating laboratories in Yorkshire for analysis. After the results are generated any remaining sample will be destroyed according to the usual blood disposal procedures.

The central laboratory (LGI) will retain some of the sample frozen for future testing. Confidential sample and result handling will include:

- Anonymous samples and results
- Samples will only be used for reference interval work
- Only the researchers and participating laboratories will access to samples
- No samples will be transferred outside the UK.

WILL ANY GENETIC TESTS BE DONE?

No genetics tests will be done.

WHAT WILL HAPPEN TO THE RESULTS OF THIS STUDY?

We intend to send a summary of the findings to everybody who participates in the research. We also hope to publish the results in a medical journal.

WHO IS ORGANISING AND FUNDING THIS STUDY?

The Blood Sciences Department of Leeds General Infirmary will fund the bulk of this work by carrying out the analysis of blood samples.

WHO HAS REVIEWED THE STUDY?

It has been reviewed and given a favourable outcome by the Bradford Research and Ethics Committee.

CONTACT FOR FURTHER INFORMATION

If you think you might like to take part in the study, please contact us so that we can discuss it with you and arrange a time for you to come to our testing centre. You can contact the researchers (Julian H Barth and Ahai Luvai) using the details below.

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